REMARKS

Amendments of the Claims

Claims 2-4, 18-20, 30-32, and 40 have been amended as set forth in the above Complete Listing of the Claims. As amended, the claims are supported by the specification and the subject matter recited in the original claims. No new matter (35 U.S.C. § 132) has been added.

Claim 17 has been indicated as allowable and claims 18 and 19 were indicated as allowable if rewritten in independent form. Accordingly, claims 18 and 19 have been rewritten in independent form.

Thus, upon entry of the amendments, claims 2-6 and 8-48 will be pending, of which 17-19 are allowed or indicated allowable.

Rejection of Claims Under 35 U.S.C. §102

Claims 32, 40 and 41 have been rejected under 35 U.S.C. 102(b) as being anticipated by Flick (2001) in light of Garcia (2005). Applicant traverses such rejection.

Anticipation of a claim requires the disclosure in a single prior art reference of each element of the claim under consideration. (In re Spada, 15 USPQ2d 1655 (Fed. Cir., 1990), In re Bond, 15 USPQ2d 1566 (Fed. Cir., 1990).

Claims 32, 40 and 41 all recite a dermatological composition "wherein said dermatological composition is free of parabens." The cited Flick composition, however, contains a preservative "Uniphen-23" in Sequence 1. Appendix A of this response contains an April 3, 2007 screen capture of the website of the company Induchem AG, manufacturer of Uniphen-23. The company's website describes its product Unophen-23 as a preservative with INCI (International Nomenclature Cosmetic Ingredient) names including methylparaben, ethylparaben, butylparaben, propylparaben and isobutylparaben. Uniphen-23 thus is a paraben material.

Since Flick teaches compositions containing parabens, and fails to describe any dermatological composition that is devoid of parabens, Flick cannot anticipate the applicant's claimed invention as set forth in claims 32, 40 and 41, because each of such claims 32, 40 and 41 recites a dermatological composition that "is free of parabens."

Accordingly, withdrawal of the rejection of claims 32, 40 and 41 under 35 U.S.C. § 102(b) as

being anticipated by Flick, and evidenced by Garcia, is respectfully requested.

Rejection of Claims Under 35 U.S.C. §103

Claim 40 has been rejected under 35 U.S.C. §103(a) as unpatentable over Flick (1989). Applicant traverses such rejection.

In order for an invention to be obvious, the difference between the subject matter of the application and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art. In order to meet this standard, the combination of references must teach or suggest all of the elements of the claimed invention. See MPEP§ 2143.03:

2143.03 All Claim Limitations Must Be Taught or Suggested

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

It is respectfully submitted that Flick (1989) does not teach or suggest all of the elements of the claimed invention.

Amended claim 40 recites the transitional phrase "consisting essentially of." It is well settled that this transitional phrase "limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. (*In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). (emphasis in original)) Accordingly, the scope of claim 40 is limited to the specified materials therein and those additional components that do not materially affect the claimed composition.

Claim 40 specifically claims a composition "consisting essentially of...at least one emollient selected from the group consisting of Butyrospernum Parkii (Shea butter) fruit, glycine soja (soybean) sterol and Helianthus Annuus (hybrid sunflower) oil..." Inclusion of emollients beyond those claimed would affect the basic and novel characteristics of the dermatological composition of claim 40. While the composition of Flick (1989) includes hybrid sunflower seed

oil as an emollient, it also includes PPG-15 stearyl ether and dioctyl adipate, both emollients. As such, Flick (1989) fails to teach or in any way to suggest a dermatological composition "consisting essentially of...at least one emollient selected from the group consisting of Butyrospernum Parkii (Shea butter) fruit, glycine soja (soybean) sterol and Helianthus Annuus (hybrid sunflower) oil...". Flick (1989) therefore does not teach or suggest all element of the claimed invention.

Since Flick (1989) fails to teach or suggest a composition as claimed in claim 40, Flick (1989) cannot render the claimed invention obvious.

Withdrawal of the rejection of claim 40 under 35 U.S.C. § 103(a) as being obvious over Flick (1989) is therefore respectfully requested.

In addition, claims 2-6 and 8-16 and 20-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,485,733 B1 (hereinafter "Huard et al.") in view of Nagel et al. (1977) and further in view of U.S. Patent No. 6,180,133 B1 (hereinafter "Quan et al."), U.S. Patent No. 5,997,889 (hereinafter "Durr et al."), U.S. Patent No. 4,233,295 (hereinafter "Hill et al.") and U.S. Application No. 2005/0048105 A1 (hereinafter "McNulty et al."). This rejection was maintained from the previous Office Action mailed July 31, 2006. Applicant respectfully traverses such rejection, based on the fact that the cited combination of references does not teach or suggest all elements of the claimed invention.

Of the rejected claims, claims 32, 40, 41 and 42 are independent claims, and all remaining claims depend directly or indirectly therefrom. Claims 32, 40, 41 and 42 all recite a composition that is "free of parabens." As stated in the Response to the Office Action mailed July 31, 2006, the cited combination of references does not teach or suggest applicant's composition.

For a legally proper rejection under 35 USC §103, a combination of references cited as rendering an invention obvious must teach or suggest all of the elements of the claimed invention. See MPEP §2143. The reference combination of Huard in view of Nagel et al. and further in view of Quan et al., Durr et al., Hill et al. and McNulty et al. does not teach or suggest all of the elements of applicant's claimed invention.

Applicant has previously pointed out that Huard et al. does not teach or suggest a composition of the claimed invention. In particular, Huard et al. does not teach or suggest a composition that contains a humectant including at least one of urea and ammonium lactate (claims 14, 17, 32, 40

and claims dependent therefrom), and Huard et al. does not teach or suggest a composition free of parabens. By its prior statement, the applicant was not intending to argue against Huard et al. individually, but was intending to show the elements that were missing from Huard et al. and would at a minimum need to be taught or suggested by other references in order for the claimed invention to be obvious. Accordingly, Huard et al., in order to present a *prima facie* case, would need to be cited with reference(s) that teach or suggest a composition containing a humectant including at least one of urea and ammonium lactate and a composition that is free of parabens. The cited references, in combination, do not teach or suggest such a composition.

Nagel et al. does not teach or suggest the elements missing from Huard et al. Specifically, Nagel et al. does not teach or suggest a composition that contains a humectant including at least one of urea and ammonium lactate, nor a composition that is free of parabens. While Nagel et al. does teach that some people suffer from paraben allergies, there is no motivation to combine this teaching with the composition of Huard et al., based on the actual content of the references.

The examiner states that "Nagel et al., taken as a whole, clearly teaches that creating formulations without parabens would be advantageous for people with paraben allergy." However, this discussion of parabens relates to allergic reactions to parabens in formulations that were administered intravenously or subdermally, but not topically. Applicant's claimed composition, by contrast, is a dermatological composition, i.e., for topical use.

The examiner has further stated that "[i]t is not accepted that Nagel et al. teach the opposite in that ... 'a patient with a known paraben allergy when the paraben is administered intravenously may not have an allergy to [topical] administration of parabens.'" It is unclear how the examiner can take the position that the Nagel et al. reference does not teach the above. While the patient described in the reference was not diagnosed with the allergy prior to his hospitalization, the adverse reaction in the hospital was from intravenous administration of "a hydrocortisone preparation containing methylparaben and propylparaben" (p. 1994, 3rd col.) and confirmed by later controlled administration of the same. Applicant does not argue that the subject of the Nagel et al. reference had an adverse reaction to intravenous paraben administration.

However, applicant points out that the same subject who had an adverse reaction to intravenous administration of paraben had previously used parabens topically, without any adverse reaction:

"He [the patient] had intermittently used paraben-containing

> topical cortocosteroids and lubricating creams for treatment of his atopic dermatitis; however he had never experienced adverse cutaneous reactions to any of these preparations." (p. 1995, 2d col., emphasis added)

Furthermore, all skin tests performed with parabens (Table 1) were performed intradermally. Nagel et al. does not teach or suggest patients with allergy or sensitivity to topical administration of parabens. Nor would any solutions offered by Nagel et al. be necessarily applicable to those with such a topical sensitivity.

The examiner's conclusion regarding the Nagel et al. reference is that "the reference clearly establishes the need for paraben-free 'drugs, foods and cosmetics (p. 1995) for people who have been diagnosed with paraben allergies." Applicant respectfully disagrees with this conclusion. Nagel et al.'s results apply to those with an allergy or sensitivity to intradermal or intravenous paraben administration. Nagel et al. does not describe any subject with a topical sensitivity to parabens. In fact, Nagel et al.'s one patient with intravenous sensitivity showed a lack of reaction to topical administration of parabens, as set forth above.

Nagel et al.'s conclusions lead to the statement in the final paragraph of that reference that "[t]his case of immediate hypersensitivity to methylparaben and propylparaben demonstrates that parabens should not be used indiscriminately as preservatives, especially not in medications [oral administration] frequently given to the allergic or potentially allergic patient." (emphasis added.) This statement allows for use of parabens discriminately as preservatives and in medications infrequently given to allergic or potentially allergic patients. Nagel et al. does not teach paraben-free "drugs, foods and cosmetics," but suggests that new labeling requirements might help those with sensitivity avoid such ingredients. However, the sensitivity discussed by Nagel et al. relates to intravenous sensitivity, which can exist without sensitivity to topical administration. Applicant's invention relates to a dermatological composition, i.e., a composition for topical use.

It is stated in the Office Action mailed January 4, 2007 that one of skill in the art would have used the teaching of paraben allergies in Nagel et al. to provide a composition of Huard et al. that was further free of parabens. Applicant respectfully disagrees.

One of skill in the art would not have had a motivation to combine the two teachings. One of skill would not have taken a reference regarding avoidance of parabens for those with sensitivity to intravenous administration of parabens and combined its teachings with a topical composition to generate a paraben-free topical composition. In fact, Nagel et al. teaches away from such a

combination, by demonstrating that the subject therein had used paraben-containing topical treatments without adverse reaction. Therefore, there would be no incentive for such a patient to refrain from topical use of parabens.

The combination of the teachings of Huard et al. in view of Nagel et al. does not yield a composition of applicant's claimed invention, since the cited references do not teach or suggest a composition that comprises urea and/or ammonium lactate, and do not teach or suggest a composition that is free of parabens. Accordingly, Huard et al. in view of Nagel et al. does not teach or suggest all of the elements of the claimed invention. The references Quan et al., Durr et al., Hill et al. and McNulty et al. do not teach the elements missing from the combination of the Huard et al. and Nagel et al. references.

Quan et al. is cited as teaching or suggesting the addition of ammonium lactate to a composition of Huard et al. in view of Nagel et al.

Durr et al. is cited as teaching or suggesting addition of shea butter to a composition of Huard et al. in view of Nagel et al.

Hill et al. is cited as teaching or suggesting addition of butylated hydroxytoluene to a composition of Huard et al. in view of Nagel et al.

McNulty et al. is cited as teaching or suggesting addition of sodium polyacrylate to a composition of Huard et al. in view of Nagel et al.

However, none of the cited references taken in combination with one another teaches or suggests a composition that comprises urea or ammonium lactate and that is free of parabens or any composition that is free of parabens.

As Huard et al. in view of Nagel et al. and further in view of Quan et al., Durr et al., Hill et al., and McNulty et al. does not describe or suggest a composition as set forth in claims 2-6 and 8-16 and 20-48, Huard et al. in view of Nagel et al. and further in view of Quan et al., Durr et al., Hill et al., and McNulty et al. does not render the claimed invention obvious. Accordingly, withdrawal of the rejection of claims 2-6 and 8-16 and 20-48 under 35 U.S.C. § 103 (a) as being obvious over Huard et al. in view of Nagel et al. and further in view of Quan et al., Durr et al., Hill et al., and McNulty et al. is respectfully requested.

Fee Payable for Rewritten Claims 18 and 19

The fee of $200 for the addition of two independent claims incident to the rewriting of claims 18 and 19 in independent form is enclosed in the accompanying Credit Card Authorization Form directing such payment to the credit card specified in such Form.

Authorization also is hereby given to charge the amount of any additional fees or amounts properly payable in connection with the filing and entry of this Response, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

CONCLUSION

Based on the foregoing, all of applicant's pending claims 2-6 and 8-48 are patentably distinguished over the art, and are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

No fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

Date:April 4, 2007

/steven j. hultquist/
Steven J. Hultquist
Reg. No. 28,021
Attorney for Applicant

Date:April 4, 2007

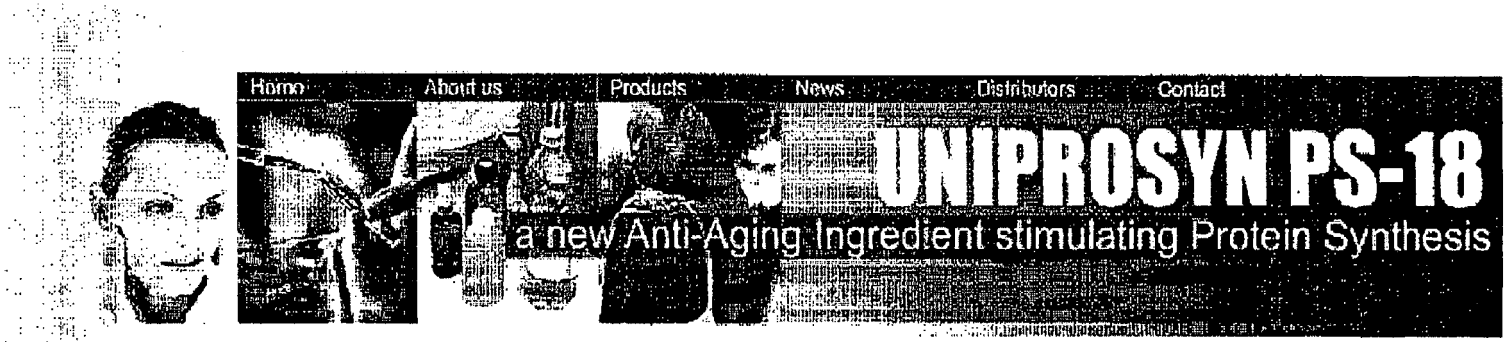
/kelly k. reynolds/
Kelly K. Reynolds
Reg. No. 51,154
Attorney for Applicant

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
Phone: (919) 419-9350
Fax: (919) 419-9354
Attorney File No.: 4237-101

Enclosures:
Appendix A

The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284

APPENDIX A



Products / Preservatives — UNIPROSYN PS-18

TRADE NAME	APPLICATION	ACTIVITY	SOLUBILITY	REGULATORY STATUS	INCI name
	soaps, deodorants, cosmetics with plant-based active ingredients				
Uniphon P-23	All cosmetics in a pH range of 3.0-8.0	Bactericide and fungicide	Water soluble at 0.5% Oil soluble	EU allowed USA allowed Japan allowed	Phenoxyethanol Methylparaben Ethylparaben Butylparaben Propylparaben Isobutylparaben
Unisuprol S-25	All cosmetics in a pH range of	Bactericide and fungicide	Water soluble at 0.6%	EU allowed USA allowed	Phenoxyethanol Triethylene Glycol

● SAMPLES/TECHNICAL INFORMATION REQUEST

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Induchem AG - Industriestrasse 8a - CH-8834 Volketswil - [illegible]
Induchem USA, Inc. - 540 Madison Avenue, 20th Floor - New York, NY 10022 - sales.usa@induchem.com

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